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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,857	12/31/2001	Dilip Wagle	361331-512	4034

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EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 04/23/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,857

Applicant(s)

WAGLE ET AL.

Examiner

Hong Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 35-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 27-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-49 are pending in this application. The original claims are misnumbered. There is no claim 22 after claim 21. Original claim 23 is renumbered as claim 22 and the rest of the claims following original claim 23 are also renumbered accordingly.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19, drawn to a method of treating an indication of the invention classified in class 514, subclass 355.
 - II. Claims 20-26, drawn to the compounds of formula VI, classified in class 548 and its corresponding subclasses.
 - III. Claims 27-34, drawn to the compounds of formula VII, classified in class 546, subclass 316.
 - IV. Claims 35-43, drawn to the compounds of formula VIII, classified in class 544 and its corresponding subclasses.
 - V. Claims 44-49, drawn to the compounds of formula IX, classified in class 548 and its corresponding subclasses.

The inventions are distinct, each from the other because of the following reasons:

Groups II-V are directed to structurally dissimilar compounds such that the variable core created by varying the definitions of the formula do not belong to a recognized class of chemical compounds in the art, and references anticipating one invention would not render obvious the others, for example, pyrimidine and pyridine, etc. are different from thiadiazole or triazole, etc. Thus, separate searches in the literature as well as in the U.S. Patent Clarification System would

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be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structures as functional equivalents of each other. The mere fact that there is a single similarity is not in itself a significant reason to render the whole embodiment obvious.

Inventions I and II-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case more than one use exists for compounds of Group I as evidenced by claims 1-19 drawn to a variety of diverse uses. Additionally, the various uses would raise issues of enablement separate from that of the compound claims and would require art-recognized evidence that activity relied on its reasonably correlated to in vivo efficacy for the uses claimed.

2. During a telephone conversation with Dr. Arthur Jackson on April 15, 2003 a provisional election was made with traverse to prosecute the invention of Group III, claims 27-34.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-26 and 35-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants also elected a species, Example 2. The elected compound was not found to be anticipated in the search and the search was expanded to compounds wherein the phenyl is substituted by more than one chloro.

Applicants are also advised of MPEP 803.02, Restriction -Markush Claims[R-2], forth paragraph, where is stated;

4. “As an example, in the case of an application with a Markush -type claims drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn form further consideration. As in the prevailing practice, **a second action on the rejected claims would be made final.**” (Emphasis added).

Priority

5. Applicant’s claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 27-34 of this application. Provisional Application No. 60/259,294 filed more than one year before filing of the non-provisional application. Provisional

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applications 60/259,238 and 60/296,246 do not have support of the compounds in the present application where R13 is carbamoyl. ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 27, 28, 30, 31, 33, and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Sankaranarayanan et al. (WO 01/25209). Sankaranarayanan teaches the compounds and composition of the instant invention (see Example 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 28, 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sankaranarayanan et al. (WO 01/25209). The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I, page 6 wherein R1 is Y-R3 wherein R1 is NH and R3 is hydrogen or alkyl, R2 is an optionally substituted aryl. The compounds are taught to be useful as pharmaceutical agents. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, it would have nevertheless been obvious to one skilled in the art at the time of the invention to be motivated to select any of the species of the genus taught by the reference including those

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instantly claimed, because the skilled chemist would have the reasonable expectation that any of the specie of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. See *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-31 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preparation and use of compounds wherein R13, R14, R15, and R16 do not form ring systems, does not reasonably provide enablement for preparation and use of compounds wherein R13, R14, R15, and R16 form ring systems. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The nature of the invention in the instant application has claims which embrace a diversity of chemically and physically distinct compounds, wherein R13, R14, R15, and R16 can form ring systems, unsubstituted or substituted, aromatic or an unsubstituted or substituted, heteroaromatic group, containing one or more heteroatoms, etc. While four compounds are

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disclosed, there is insufficient guidance for preparing additional compounds which would be effective since the cited examples are drawn to a homogenous group of compounds not remotely commensurate in scope to applicants' claims. Only compounds wherein R13, R14, R15, and R16 do not form ring systems have been made.

Furthermore, testing data is limited to a number of compounds not considered to be representative of all the possible compounds encompassed by the claims. Examples should be of sufficient scope as to justify the scope of the claim. However, the generic claims are much broader in scope than is represented by the testing. The definitions of R13, R14, R15, and R16 variables embrace many structurally divergent groups not represented at all in testing, since testing for the instant compounds is not seen in the specification. Markush claims must be provided with support in the disclosure when the "working examples" fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms. See *In re Fouch*, 169 USPQ 429.

This area of activity can be expected to be highly structure specific and unpredictable, as is generally true for chemically-based pharmacological activity. In view of the structural divergence in the claims, one skilled in the art could not reasonably extrapolate the activities of some of the claimed compounds to the other structurally divergent compounds embraced by the claims which have not been tested. In cases directed to chemical compounds which are being used for their physiological activity, the scope of the claims must have a reasonable correlation to the scope of enablement provided by the specification. See *In re Surrey* 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. No reasonable assurance has been made

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that the instant compounds as an entire class have the required activities needed to practice the invention.

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability” have been demonstrated to be sufficiently lacking in the instant case for the scope being claimed.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1). The use of “heterocyclic” in the definition of R13, R14, R15, and R16 in claim 27 is unclear to the array of heteroatoms, size of the rings, as well as nature of atoms as ring members. See *In re Wiggins* 179 USPQ 421 for certain terminology regarding heterocyclic ring systems.

2). Claim 30 recites the limitation “cyano or Rs” in R6. There is insufficient antecedent basis for this limitation in the claim.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner’s supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for “unofficial” purposes and the actual number for official business is (703) 308-4556. Any inquiry of a general nature or relating to the


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status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

hl
April 19, 2003


Mukund Shah
Supervisory Patent Examiner
Art Unit 1624